

Maine Revised Statutes

Title 22: HEALTH AND WELFARE

Chapter 602-A: access to investigational treatments for terminally ill patients

§2671. DEFINITIONS

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings. [2015, c. 418, §1 (NEW).]

1. Eligible patient. "Eligible patient" means a person who has:

A. Received a diagnosis of a terminal illness for which no standard treatment is effective and the diagnosis has been attested by the person's treating physician; [2015, c. 418, §1 (NEW).]

B. Considered all treatment options approved by the United States Food and Drug Administration; [2015, c. 418, §1 (NEW).]

C. Not been accepted into a clinical trial within one week of completion of the clinical trial application process; [2015, c. 418, §1 (NEW).]

D. Received a recommendation from the person's treating physician for an investigational drug, biological product or device; [2015, c. 418, §1 (NEW).]

E. Given written, informed consent for the use of the investigational drug, biological product or device under paragraph D or, if the person is a minor or lacks the mental capacity to provide informed consent, whose parent or legal guardian has given written, informed consent on the person's behalf; and [2015, c. 418, §1 (NEW).]

F. Received documentation from the person's treating physician that the person meets all of the conditions in this subsection. [2015, c. 418, §1 (NEW).]

[2015, c. 418, §1 (NEW) .]

2. Investigational drug, biological product or device. "Investigational drug, biological product or device" means a drug, biological product or device that has successfully completed Phase I of a United States Food and Drug Administration-approved clinical trial but has not yet been approved for general use by the United States Food and Drug Administration and remains under investigation in such a clinical trial.

[2015, c. 418, §1 (NEW) .]

3. Terminal illness. "Terminal illness" means a disease or condition that, without life-sustaining measures, will soon result in death or in a state of permanent unconsciousness from which recovery is unlikely.

[2015, c. 418, §1 (NEW) .]

4. Treating physician. "Treating physician" means a physician who has primary responsibility for the care of a patient and treatment of that patient's terminal illness.

[2015, c. 418, §1 (NEW) .]

5. Written, informed consent. "Written, informed consent" means a written document signed by a patient or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian of the patient. The document must be attested by the patient's treating physician and a witness and include the following information:

- A. An explanation of the United States Food and Drug Administration-approved treatments for the disease or condition from which the patient suffers; [2015, c. 418, §1 (NEW).]
- B. A statement that the patient concurs with the patient's treating physician that all United States Food and Drug Administration-approved and standard treatments for the disease or condition from which the patient suffers are unlikely to prolong the patient's life; [2015, c. 418, §1 (NEW).]
- C. Clear identification of the specific investigational drug, biological product or device that the patient is seeking to use; and [2015, c. 418, §1 (NEW).]
- D. A description of the best and worst potential outcomes of using the investigational drug, biological product or device identified under paragraph C with a description of the most likely outcome. The description must include the possibility that new, unanticipated, different or worse symptoms might result and that death could be hastened by the proposed treatment. The description must be based on the treating physician's knowledge of the proposed treatment in conjunction with the treating physician's knowledge of the patient's overall medical condition. [2015, c. 418, §1 (NEW).]

[2015, c. 418, §1 (NEW) .]

SECTION HISTORY

2015, c. 418, §1 (NEW).

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